

REMARKS

Claims 1-17 remain pending in this application.

Claims 15 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goto *et al.* (EP 0,389,700) for the reasons set forth on page 4 of the Office Action. Applicants respectfully traverse.

Goto discloses soft capsules and globular material made from an agar agar base material. In Goto, agar agar is used as the *only* carbohydrate film material. The present invention, in contrast, is directed to a *matrix* of polymeric carrier comprising only *1 to 7% prehydrated* agar agar. As explained in the specification, the use of such relatively small and specific amounts of prehydrated agar agar in a polymeric matrix is a critical and novel feature of the present invention, which results in the formation of a gel layer in water and therefore stability in aqueous environments for a prolonged period of time. This facilitates and enables controlled release of active ingredients encapsulated therein (*see* published application, paragraphs [0025]-[0028]).

The fact that such a small amount of agar agar can be used so effectively is particularly surprising from the process point of view, since, for example, viscosity constitutes a limiting factor in determining the amount of hydrocolloid that can be used in an extrusion process (paragraph [0028]). Thus, the small concentration of agar agar in the present delivery system is completely unexpected and represents an essential characteristic of the present invention.

Furthermore, the use of prehydrated agar agar, another critical feature of the present invention, is neither disclosed nor suggested in Goto. Because of the use of prehydrated agar agar, the present delivery system shows an unexpected and advantageous behavior in an aqueous environment as displayed during the rehydration process (*see* paragraph [0041]). Rehydration of the polymeric carrier that includes prehydrated agar agar results in the rapid formation of a gel layer at the surface of the present product, thus preventing loss of flavor or fragrance ingredients to the surrounding water. Such flexible gel barrier is broken into smaller gelled pieces upon application of strong pressure, releasing flavor or fragrance ingredient at the fracture points only.

Therefore, the present invention achieves such advantages as gel barrier formation in aqueous environment, prolonged stability in water and controlled release of active ingredients by utilizing specific amounts of agar agar in a particular manner in a granular delivery system

that is completely different from the prior art. Accordingly, Applicants respectfully request that the obviousness rejection based on Goto be withdrawn.

Claims 1-11 and 15-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Barnes *et al.* (WO 85/03414) for the reasons set forth on pages 4-6 of the Office Action.

Barnes teaches an encapsulating matrix composition with an improved loading capacity, comprising maltodextrin, hydrogen octenylbutanedioate amylopectin (modified starch) and, optionally, an emulsifier, examples of which include agar agar. Barnes seeks to improve the loading capacity of the encapsulating matrix by combining maltodextrin and modified starch, which is used to absorb the oil of the active ingredient and to hold the ingredient (page 5, lines 20-23). Since agar agar is not a required element of the carrier matrix but only an optional emulsifier, Barnes does not disclose a single example of a composition that actually contains agar agar. For the same reason, Barnes fails to recognize and utilize the advantages of agar agar when used in capsules and put into water.

In contrast to the Barnes' encapsulating matrix composition, the present granular delivery system is based on a completely different concept and requires prehydrated agar agar in a specific amount as part of the matrix of polymeric carriers. As explained above, Applicants have unexpectedly discovered that agar agar can be advantageously used in relatively very small amounts, in combination with a carbohydrate material, in the matrix composition of an extruded system. Such unique use of prehydrated agar agar enables the present delivery system to have increased stability in aqueous environments and to release encapsulated active ingredients in a controlled manner.

Moreover, because an emulsifier or agar agar is not an essential ingredient of the Barnes composition, Barnes does not specify how agar agar should be employed in its encapsulating composition. Unlike Barnes, the manner of using agar agar, *i.e.*, using a prehydrated agar agar in specific, relatively low amounts, is an important and advantageous feature of the present invention, as detailed in the specification (*see* paragraph [0049] ("the agar agar is mixed with approximately 11 times its weight in water and allowed to rehydrate. . ."). As Applicants have noted in paragraph [0016] of the specification, while agar agar has been previously recognized to have film forming and bioadhesive properties, it has only appeared in the prior art "as part of the all encompassing list of gums, hydrocolloids, film forming agents and bioadhesives," and not specifically exemplified. Barnes' mention of agar agar as an emulsifier is one such example of the prior art which lists agar agar merely as a

possibly useful material but does not recognize the specific advantages of employing prehydrated agar agar in a particular manner as surprisingly discovered by the present applicants.

Hence, given that neither the agar agar itself nor the manner of its use is an important part of the Barnes composition, the present invention, whose critical features include the incorporation of a specific quantity of prehydrated agar agar in a specified manner, cannot be considered obvious in light of Barnes. Accordingly, Applicants respectfully submit that this claim rejection is inappropriate and should be withdrawn.

Finally, claims 12-14 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over Sair *et al.* (U.S. Patent No. 4,232,047).

Sair discloses a food supplement concentrate of an ingestible agent encapsulated as a dispersed microphase within a matrix of encapsulating medium such as starch, protein, flour, modified starch, gum and mixtures thereof. Sair is completely silent on the use of agar agar, let alone the specific quantities of agar agar to be used or the manner of its employment. Further, agar agar as used in the present invention is different from each of the encapsulating medium mentioned in Sair, namely, starch, flour, gum, cereal, and protein. A soluble carbohydrate isolated from algae, agar agar cannot be equated with a typical gum isolated from plants. That the prehydrated form of agar agar, and not just any gum, is used in the present invention further emphasizes the differences between the encapsulating materials used in the present invention and Sair.

In fact, rather than rendering the present invention obvious, Sair teaches away from the present invention by stating that: "The essence of the present invention does not lie . . . *in the selection of any specific encapsulating material* as a protective matrix" (col. 6, lines 22-26) (emphasis added). By destressing the role of the encapsulating material and teaching that the choice of the material should not affect encapsulation, Sair leads one skilled in the art away from looking at particular matrix components. Given the teachings from Sair, a person skilled in the art would have no motivation to modify Sair, which does not even mention agar agar, to arrive at the present invention and the resulting advantages that are unexpectedly obtained by using a specific quantity of a specific matrix material in a specific manner. Thus, the rejection based on Sair should also be withdrawn.

Accordingly, Applicants respectfully request that all rejections under § 103 be withdrawn, as none of the prior art references renders the present claims obvious as shown by the preceding explanation.

In view of the above, the entire application is believed to be in condition for allowance, early notification of such would be appreciated. Should the Examiner not agree, a personal or telephonic interview is respectfully requested to discuss any remaining issues in order to expedite the eventual allowance of the claims.

Respectfully submitted,

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Allan A. Fanucci 30,256
(Reg. No.)

WINSTON & STRAWN LLP
CUSTOMER NO. 28765
(212) 294-3311